United Nations
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Research Institute

Role, duties and responsibilities of CT's personnel

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MAIN ROLE, DUTIES AND RESPONSIBILITY OF INVESTIGATOR ACCORDING TO GCP

4.1 INVESTIGATOR'S QUALIFICATIONS AND AGREEMENTS

- 4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial.

- 4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

- 4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

4.2 ADEQUATE RESOURCES

- 4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

- 4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

4.3 MEDICAL CARE OF TRIAL SUBJECTS

- 4.3.1 A qualified physician, who is an investigator or a subinvestigator for the trial, should be responsible for all trial-related medical decisions.

4.5 Compliance with Protocol

- 4.5.1 The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies) and which was given approval/favourable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.

- 4.5.2 The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s).

4.5 Compliance with Protocol

- 4.5.4 As soon as possible, the implemented deviation or change, the reasons for it, should be submitted:
  - To the IRB/IEC for review and approval/favourable opinion,
  - To the sponsor for agreement and, if required,
  - To the regulatory authority(ies)

4.6 INVESTIGATIONAL PRODUCT(S)

- 4.6.1 Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.

- 4.6.2 The investigation/institution may/should assign accountability to an appropriate pharmacist.

4.7 RANDOMIZATION PROCEDURES AND UNBLINDING

- The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol.

4.8 INFORMED CONSENT OF TRIAL SUBJECTS

- 4.8.5 The investigator, or a person designated by the investigator, should fully inform the subject of all pertinent aspects of the trial including the written information.

4.9 RECORDS AND REPORTS

- 4.9.1 The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

- 4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial.

4.10 PROGRESS REPORTS

- 4.10.1 The investigator should submit written summaries of the trial status to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC

- 4.10.2 The investigator should promptly provide written reports to the sponsor, to the IRB/IEC and, where applicable, the institution on any changes significant affecting the conduct of the trial, and/or increasing the risk to subjects.

4.11 SAFETY REPORTING

- 4.11.1 All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g. Investigator's Brochure) identifies as not needing immediate reporting.